

REMARKS

Claims 25-27, 31-35, 40, 43-52 and 55-75 are pending, with claims 51, 52 and 57-65 and 71-75 having been withdrawn from further consideration. By the present communication, Applicants have canceled claims 51, 52, and 57-65 without prejudice, and amended claims 25, 34, 35, 66, 71 and 74 to define Applicants' invention with greater particularity. The amendments do not raise any issues of new matter and the amended claims do not present new issues requiring further consideration or search. Applicants note that claims 71 and 74 were amended to correct a typographical error in their dependency. Support for the amendment to claims 71 and 74 may be found, among others, in Examples 3-5 of the specification as filed. Accordingly, upon entry of this communication, claims 25-27, 31-35, 40, 43-50, 55, 56, and 66-75 will be under consideration.

As suggested by the Examiner, Applicants submit a terminal disclaimer disclaiming the terminal part of any patent granted on the above-identified Application No. 10/662,003 that would extend beyond the expiration date of U.S. Patent No. 6,673,534.

Priority

Applicants traverse the accord of priority of the present application to November 10, 1997. Specifically, the Office alleges that the parent applications does not have any written support for the method of detection pertaining to the specific species of bovine as claimed. Applicants maintain that the parent application fully supports claims directed to a method for detecting the presence of a target myostatin variant nucleic acid sequence in a nucleic acid-containing specimen wherein the specimen is from a subject having increased muscle mass or having a predisposition for increased muscle mass as compared to a subject having a wild-type nucleic acid sequence. Specifically, the priority application provides support for the importance of the mature or C-terminal region of the myostatin polypeptide, where exon 3 and the specific 11 base-pair mutation are found. Finally, Applicants were the first to clone the bovine myostatin sequence, which is provided in the priority applications as well, and deposited in GenBank as

accession no. AF019620. Accordingly, accord of the benefit of priority to at least as early as **October 26, 1995** is respectfully requested.

Objection to the Claims

Applicants respectfully traverse the objection to claim 50 for allegedly containing a typographical error. However, in order to further prosecution and reduce the issues, Applicants have amended claim 50 to correct the claim dependency. Withdrawal of the objection is respectfully requested.

Rejection under 35 U.S.C. §112, Second Paragraph

Applicants respectfully traverse the rejection of claims 66-70 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office alleges that claim 66 does not require that the bovine subject be Belgian Blue, but rather that the Belgian Blue myostatin variant nucleotide sequence be detected from the genus of bovine species. In order to further prosecution and reduce the issues, Applicants have amended claim 66 to recite that the specimen is from Belgian Blue. Support for the amended claim language may be found, among others at page 5, line 4. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §112, First Paragraph

Applicants respectfully traverse the rejection of claims 25-27, 31-40, 55 and 56 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Office alleges that the specification does not reasonably provide enablement for a method for detecting the presence of a target myostatin variant nucleic acid sequence in a nucleic acid specimen, wherein the specimen is avian, ovine, piscine, baboon, murine, or porcine, wherein the target myostatin variant nucleotide is any variant myostatin sequence, and wherein the variant sequence is found in only one allele. Applicants note that claims 36-39 were canceled in the Response filed June 30, 2006, rendering the rejection moot as to those claims. In

order to further prosecution and reduce the issues, Applicants have amended claim 25 to limit the claims to detecting the presence of a variant Piedmontese myostatin having a homozygous G1056A substitution, wherein the specimen is from Piedmontese, as suggested by the Examiner. Support for the amended claim language may be found, among others, at page 5, lines 9-10, and at page 34, lines 7-13. Accordingly, withdrawal of the rejection is respectfully requested.

Applicants respectfully traverse the rejection of claims 66-70 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Office alleges that the specification does not reasonably provide enablement for a method for detecting the presence of a target myostatin variant nucleic acid sequence in a nucleic acid specimen, wherein the specimen is bovine, and wherein the variant myostatin nucleotide sequence has a deletion of nucleotides 937-947 in the 3rd exon. In order to further prosecution and reduce the issues, Applicants have amended claim 66 to limit the claims to detecting the presence of a variant Belgian Blue myostatin having a homozygous deletion of nucleotides 937-947 in the 3rd exon, wherein the specimen is from Belgian Blue, as suggested by the Examiner. Support for the amended claim language may be found, among others, at page 33, lines 25-30. Accordingly, withdrawal of the rejection is respectfully requested.

Applicants respectfully traverse the rejection of claims 34 and 35 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Office alleges that the specification does not reasonably provide enablement for a method of detection for Piedmontese myostatin variant nucleotide sequence having a homozygous G1056A substitution, wherein the probe hybridizes to SEQ ID NO: 6, and wherein the probe is SEQ ID NO: 10. In order to further prosecution and reduce the issues, Applicants have amended claims 34 and 35 to remove SEQ ID NO: 6 and SEQ ID NO: 10, respectively. Accordingly, withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §102

Applicants respectfully traverse the rejection of claims 66-68 U.S.C. §102(e) as allegedly being anticipated by Grobet et al. (U.S. Pat. No. 6,103,466) (hereinafter "Grobet"). However,

Applicants submit that Grobet is not available as prior art since Applicants claim priority to patent applications dating back to October 26, 1995, over two years before the Grobet priority date. Applicants further submit herewith a declaration under 37 C.F.R. §1.131, by Drs. Se-Jin Lee and Alexandra McPherron, co-inventors of the instant application, with Exhibits 1 and 2, which demonstrates that the claimed invention was made in the United States prior to the July 14, 1997, filing date of Grobet. Accordingly, Applicants submit that Grobet is not available as prior art against the claimed invention. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §103

Applicants respectfully traverse the rejection of claims 43-46 under 35 U.S.C. §103(a) as allegedly being unpatentable over Grobet. Specifically, the Office alleges that Grobet teaches a method of detecting the presence of an 11-base pair deletion in a myostatin gene from a subject wherein the presence of the mutation is correlated with the subject having an increased muscle mass. As discussed above, Applicants submit herewith a Declaration under 37 C.F.R. § 1.131, with Exhibits 1 and 2, demonstrating that the claimed invention was made in the United States prior to the July 14, 1997 filing date of Grobet. Accordingly, withdrawal of the rejection is respectfully requested.

Applicants respectfully traverse the rejection of claims 47-50, 69 and 70 under 35 U.S.C. §103(a) as allegedly being unpatentable over Kambadur in view of Valent et al. (Molecular Microbiology, July 1997, vol. 25, no. 1, pages 53-64) (hereinafter "Valent"). As discussed above, Applicants submit herewith a Declaration under 37 C.F.R. § 1.131, with Exhibits 1 and 2, demonstrating that the claimed invention was made in the United States prior to the July 14, 1997 filing date of Grobet. Accordingly, it is submitted that Grobet is not available as prior art with respect to the claimed invention. Since Valent does not teach or suggest the claimed invention, withdrawal of the rejection is respectfully requested.

In re Application of:
Lee and McPherron
Application No.: 10/662,003
Filed: September 11, 2003
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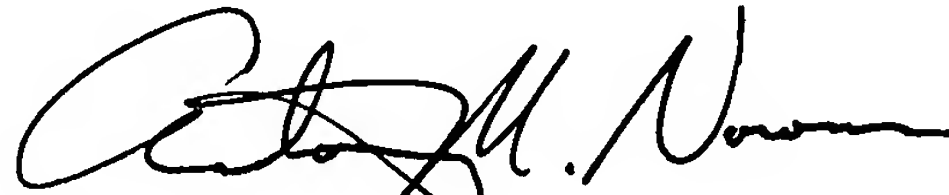
PATENT
Attorney Docket No.: JHU1410-1

CONCLUSION

In light of the Amendments and Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, he is invited to call the undersigned attorney.

Check number 584270 in the amount of \$125.00 is enclosed as payment for the Terminal Disclaimer fee (\$65.00) and Petition for One-Month Extension of Time (\$60.00). No other fee is deemed necessary with the filing of this paper. However if any fees are due, the Commissioner is hereby authorized to charge any fees, or make any credits, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number. A duplicate copy of the Transmittal Sheet is enclosed.

Respectfully submitted,



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